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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,540	06/27/2001	Masaaki Mori	56001(46342)	4354

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,540	MORI ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 19 December 2003 is acknowledged and entered. Following the amendment, claims 8-11 are canceled, claims 1, 2 and 12 are amended, and the new claims 13 and 14 are added.

Currently, claims 1, 2 and 12-14 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 8-11 are moot as the applicant has canceled the claims.

All prior art rejections made in the last Office Action are withdrawn in view of applicant's amendment.

The rejection of claims 1 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 remains rejected, and its dependent new claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the last Office Action, paper No. 9, mailed on 17 July 2003, at page 3.

The newly amended claim 2 recites two elements, the composition and a buffer. However, it is still unclear what is the interrelationship between the two elements, i.e., whether they are in a single or separate containers.

The remaining claim is rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ames et al., US 2002/0038007, in view of Maratos-Flier, US 5,849,708, and Bolton et al. (Biochem. J., 1973, 133:529-539).

The teachings of Ames, Maratos-Flier, and Bolton are reviewed in the last Office Action, paper No. 9, mailed on 17 July 2003.

Briefly, Ames discloses a human GPCR, 11cb splice variant polypeptide having SEQ ID NO:2, which is a splice variant of SEQ ID NO:11 (SLC-1) of the present invention, and teaches the MCH ligand for 11cb splice variant, which amino acid sequence is 100% identical to the MCH of SEQ ID NO:2 of the present invention; a screening method for identifying agonist or antagonist of the GPCR by binding assays in the presence of *labeled* or unlabeled MCH; and that the identified compounds would have potential therapeutic uses.

Maratos-Flier teaches MCH agonists lacking residues 1-4 of MCH, and that the minimal sequence needed to elicit an equipotent response to the native MCH is MCH(5-15), and because fragment analogs lacking residues 1-4 are equipotent to native MCH, the residues 1-4 appear to not be required for MCH activity.

Bolton teaches a reagent (Bolton-Hunter reagent) and a method using thereof for labeling of proteins such as hormones to high specific radioactivities by conjugation to a ^{125}I-containing acylating agent, and indicates that the method has the advantages such as introducing ^{125}I into peptides lacking tyrosine (as comparing to the existing methods), and avoids causes of iodination damage of the labeled peptide.

None of the references specifically teaches the ^{125}I labeled MCH(4-19) with a Bolton-Hunter reagent for a screening method as that in the present claims 1, 12 and 13, or a kit thereof (as the present claims 2 and 14).

However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to label MCH(4-19) from the indication by Maratos-Flier (that MCH(5-15) is the minimal functional sequence), with a Bolton-Hunter reagent as taught by Bolton to make ^{125}I labeled MCH(4-19) for the purpose of identifying agonist or antagonist of the receptor in a screening method taught by Ames because Maratos-Flier teaches that residues 1-4 of MCH are not required for MCH activity, and Bolton teaches that the Bolton-Hunter reagent is suitable for labeling a protein such as a hormone, with iodide. Although Maratos-Flier does not teach exclusively MCH(4-19), the reference defines the minimal functional sequence. As such, any MCH sequence comprising this minimal sequence would be obvious to be functional. The person of ordinary skill in the art would have been motivated to make such a labeled peptide for identifying the compounds having potential therapeutic uses as indicated by Ames, and reasonably would have expected success because Bolton has demonstrated the successful labeling of several hormone peptides with the Bolton-Hunter reagent.

With respect to the kit of claims 2 and 14, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said labeled protein and buffer for the purpose of research, such as screening assays as taught by Ames, because such kit would facilitate the applications, and commercial distribution. Further, packing a composition in a kit is old and well known in the art.

Claims 1, 2 and 12-14 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Salon et al, US 6,221,616 B1, in view of Maratos-Flier, US 5,849,708, and Bolton et al. (Biochem. J., 1973, 133:529-539).

The teachings of Salon are reviewed in the last Office Action, paper No. 9. Briefly, Salon teaches a variant of the present SCL-1, MCH1 receptor, which ligand is MCH having an amino acid sequence 100% identical to the present MCH of SEQ ID NO:2; a method of screening chemical compounds to identify a compound specifically binding to the MCH1 receptor by contacting cells or a membrane preparation expressing or containing said MCH1 receptor with a compound such as MCH; and that the identified compound can be used for treating diseases and disorders.

The teachings of Maratos-Flier, and Bolton are reviewed in the last Office Action, and above.

None of the references specifically teaches the ^{125}I labeled MCH(4-19) with a Bolton-Hunter reagent for a screening method as that in the present claims 1, 12 and 13, or a kit thereof (as the present claims 2 and 14).

However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to label MCH(4-19) taught by Maratos-Flier with a Bolton-Hunter reagent as taught by Bolton to make ^{125}I labeled MCH(4-19), for the purpose of identifying agonist or antagonist of the receptor in a screening method taught by Salon because Maratos-Flier teaches that residues 1-4 of MCH are not required for MCH activity, and Bolton teaches that the Bolton-Hunter reagent is suitable for labeling a protein such as a hormone, with iodide. The person of ordinary skill in the art would have been motivated to make such a labeled peptide for identifying the compounds, which can be used for treating diseases and disorders by Salon, and reasonably would have expected success because Bolton has demonstrated the successful labeling of several hormone peptides with the Bolton-Hunter reagent.

With respect to the kit of claims 2 and 14, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said labeled protein and buffer for the purpose of research, such as screening assays as taught by Ames,

because such kit would facilitate the applications, and commercial distribution. Further, packing a composition in a kit is old and well known in the art.

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Elizabeth C Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/1/04